COST RECOVERY IN THE THERAPEUTIC PRODUCTS PROGRAMME: AN OVERVIEW

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1.0 GENERAL INFORMATION

1.1 GENERAL GOVERNMENT POLICY

Cost recovery objectives

In Canada, cost recovery is a federal government policy which requires government departments to consider charging fees for services. The objectives of the policy are:

- to promote more efficient use of government services;
- to introduce more business-like and client-oriented practices in the supply of government services;
- to ensure that the costs of services which *primarily benefit the general public* are financed through taxes; and,
- to ensure that the costs of services *which primarily benefit specific subsets of the population* are recovered from those who benefit from or cause such services.

A broad policy regarding fees and departmental rights

The policy is far ranging, covering issues such as when fees are appropriate and for what, the types of fees allowed, authorities required, general guidance on the relationship of fees to costs, consultation, and monitoring.

The cost recovery policy allows departments to charge fees in order to recover the full costs of services, or the market value of rights or privileges (e.g., mining rights or broadcast licenses).

Vote Netting authority

Departments may retain revenues from these fees, up to their costs, if they have been granted Vote Netting authority. Where Vote Netting authority has been granted, the department's Appropriations funding (i.e. based on general tax revenues) is reduced by the amount of revenue anticipated from cost recovery.

1.2 INITIATING THE TPP COST RECOVERY PROGRAM

TPP begins its cost recovery program in 1995, using a four-phase process

The Treasury Board first proposed cost recovery for drug submission evaluation activity in the late 1980s. However, implementation of cost recovery was postponed until changes were made to the pre-market drug submission evaluation process.

In August 1993, as a result of a report undertaken by Dr. Denis Gagnon, a comprehensive two-year re-engineering of the Therapeutic Products Programme (TPP)* commenced, that led to a significant reduction in drug evaluation processing times. In 1994, as part of its deficit-reducing Program Review, the government cut the TPP's allocations by fifty percent; and the Treasury Board directed the TPP to implement cost recovery in fiscal year 1994-95, initiating Phase I of a four-phase cost recovery program.

By 1998, the TPP had implemented three Phases of the original plan and established a comprehensive cost recovery structure consisting of:

- five sets of fees for drug-related activities; and,
- three sets of fees for medical device activities. (Two of these are scheduled for implementation in 1999-2000.)

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* In January 1998, Health Canada amalgamated the Drugs Directorate and the Medical Devices Bureau of the Environmental Health Directorate to form the Therapeutic Products Programme.

Current status

In 1997-98, total cost recovery revenue was $39.9M, accounting for approximately two-thirds of total TPP funding. The next stage of this initiative, Phase IV, will be a comprehensive review of the impact of fees, intended and unintended, on both stakeholders and the TPP. This review, initiated in January 1999, is expected to be completed by the end of 1999.

International precedents

Canada is neither alone nor first in its decision to apply cost recovery to the regulation of drugs and medical devices. Most developed countries, including Australia, the United Kingdom and the United States have already implemented cost recovery programs for the regulation of one or both of these product groups.

1.3 THE TPP APPROACH TO COST RECOVERY

Two major factors affect the application of cost recovery

Cost recovery is a means of transferring some or all of the costs of a government activity from the general taxpayer to those who more directly benefit from, or "trigger," that specific activity. In the case of mandatory regulatory activities, according to the Treasury Board's policythe application of cost recovery is determined by two factors.

1. **Who triggers or causes the activity:** In the case of drug and medical device regulation, the pharmaceutical and medical device companies – not the taxpayer – trigger and benefit most directly from the TPP's regulatory activities. Therefore, it is appropriate that they should pay for these services.

2. **The degree to which a particular activity is a "public good" or a "private good":** All drug and medical device regulatory activities benefit the general public to some degree. However, some activities, such as authorizing the emergency sale of specialized products, primarily benefit the general public as a whole (i.e., are a "public good"); while others, such as licensing a medical device for sale, primarily benefit those individuals or groups who intend to sell the product (i.e., a "private benefit").

The concept of "shared" benefits

In recognition of the "shared" benefit of these regulatory activities, the TPP adopted a philosophy that services should be funded through a mix of Appropriations from tax revenues and cost recovery fees. (The current share of funding is about one-third from tax dollars and two-thirds from cost recovery fees.)

While the Treasury Board User Fee policy calls for fees to reflect the balance between "private" and "public" good, it fails to provide guidance on how this balance can be achieved. Phase IV, a comprehensive review of the impact of fees on stakeholders and the TPP, will attempt to incorporate this question into the review process as it relates to the TPP's activities; and help the TPP determine if and where adjustments to its cost recovery program are required.

Fee reductions for limited use/low sales drugs

The TPP also recognizes that the "public good" includes ensuring that Canadians have access to the safe and effective drugs they require, regardless of whether such drugs are in high or low demand. In defining its fees, the TPP acknowledged that high submission evaluation fees for limited use/low sales drugs would be a disincentive to manufacturers/companies applying for drug approval, resulting in limited availability. To address this issue, the TPP built fee reduction provisions into its fees structure for limited use/low sales drugs.

Activity-based costing

In the initial establishment of its cost recovery program, the TPP identified several potential "fees initiatives" based on groupings of related activities. For both drug and medical devices, these groupings were:

- pre-market submission evaluation (i.e. licensing);
- product licensing renewal; and,
- establishment licensing.

To arrive at fees for these groups of related activities, the TPP identified and costed each individual activity within each group that justified a charge. General activities (e.g., planning, policy development, administration) were similarly costed and prorated in relation to each fee initiative.

Non-mandatory services

The TPP also has activities that "stand alone" (i.e., services that are not mandatory in nature such as Drug Master Files and Export Certificates). These services, which are undertaken at the request of stakeholders, were costed separately and defined as separate fees.

Major characteristics of TPP's cost recovery program

As a result of the TPP's philosophy and approach to determining fee structures, its cost recovery program has the following characteristics:

- primarily "public good" activities, or those specifically funded

from Appropriations from general tax revenues, are not included in the costs to be recovered;

- fee-reduction provisions are provided for low sales products to mitigate the potential for adverse economic impact on companies, in an attempt to reduce the chance that necessary products will be not be available to Canadians;
- the result of the "shared" benefit philosophy and the fee-reduction provisions is that fees are always less than the full cost of the activities;
- revenue received for an activity is allocated back to the functional area responsible for that activity;
- the fee structure is intended to reflect a balance of fairness and complexity;
- an "arm's length" relationship is maintained between fee definition and collection and regulatory activities by using separate staff for these different functions; and,
- a two-stage fee appeal process is available.

1.4 THE TPP PROCEDURES: CONSULTATION AND COMMUNICATIONS

Consultation is key to TPP's success

A key element of the TPP cost recovery initiative has been extensive consultation with manufacturers, provincial partners, health care associations and consumer groups. This consultation has often taken place in a workshop format where participants come from a broad range of interest groups. The workshop setting allows each group to gain a better understanding of the needs of others and to arrive at co-operative solutions.

Consultation shapes TPP's cost recovery activities

As a result of these consultations and the recommendations of stakeholders, the TPP cost recovery initiative incorporates the following activities:

- undertaking Business Impact Tests (BITs) to provide data on the impact of cost recovery on the sectors regulated;
- ensuring that user fees are implemented in a planned, phased manner that gives all stakeholders time to adjust to the new regime;
- being sensitive to the economic and competitive concerns of industry stakeholders; and,
- making consistent and ongoing efforts to promote effective and efficient operations.

TPP's future cost recovery goals

The TPP's goal as it moves into the Phase IV review is to remain responsive to stakeholder needs, to continue to improve its operations and processes, and to maintain a flexible approach that enables it to face the continuous challenge of providing Canadians with a high quality drug regulatory system.

On the next pages, you will find descriptions of TPP's specific cost recovery programs regarding drugs and medical devices. For more information about these programs, you may contact (613) 941-8906.

2.0 THE TPP COST RECOVERY PROGRAM FOR DRUGS

Cost recovery for drugs has five components

The TPP cost recovery program for drugs has five components – three that are associated with mandatory (i.e., required by regulation) activities, and two that are non-mandatory (i.e., not required by regulations) and are a direct service to industry. These programs are described below in the order in which they were implemented.

- Authority to Sell Drugs Fees – mandatory
- Drug Submission Evaluation Fees – mandatory
- Drug Master File Fees – non-mandatory
- Drug Export Certificate Fees – non-mandatory
- Drug Establishment Licensing Fees – mandatory

2.1 "AUTHORITY TO SELL DRUGS" FEES

When implemented:

January 1, 1995

What an "Authority to Sell Drugs" fee represents:

An annual fee for the maintenance of the right to market a drug in Canada, represented by the holding of a Drug Identification Number (DIN). A DIN is obtained as the result of a successful submission to the TPP's drug evaluation activities (see 2.2).

What the fee pays for:

The TPP activities specific to the "Authority to Sell Drugs": the maintenance of information on products authorized to be marketed in Canada; post-market monitoring; and product-related investigations (e.g., resulting from trade or consumer complaints, Customs surveillance, and laboratory analysis).

Who must pay:

The company/manufacturer on record as holding the DIN.

Payments:

Payments are for the annual period beginning October 1st.

2.2 DRUG SUBMISSION EVALUATION FEES

When implemented:

September 1, 1995

What the Drug Submission Evaluation fee represents:

A fee charged to evaluate documentation submitted by a manufacturer to demonstrate the safety, efficacy and quality of a drug product for specific conditions of use. If accepted, a DIN is issued for the drug product. There are four types of submissions:

- Type I – New Drugs Submissions (NDS);

- Type II – Supplement to a New Drug Submission (SNDS);
- Type III – Abbreviated New Drug Submission (ANDS) or Supplement to an Abbreviated New Drug Submission (SANDS)
- Type IV – Drug Identification Number (DIN)

What the fee pays for:

The TPP activities specific to the evaluation of submissions as required by the Regulations under the *Food and Drug Act,* plus a portion of indirect Programme activities (e.g. policy development, planning, administration). Note: manufacturers are paying for the review of their submissions. This may or may not mean approval, depending upon the quality of the information in the submission. A sponsor must pay the fee regardless of whether the product is approved or not.

Who must pay:

All companies/manufacturers who are seeking licensing of human drug products.

Payments:

If the fee is less than $10,000, it is payable when the drug submission is filed. If the fee is greater than $10,000, then the payment schedule is as follows:

- 10% is due upon notification that the application has been screened;
- 65% is due upon notification that the application as been accepted for examination (usually concurrent with screening notification); and,
- 25% is due upon notification that the examination has been completed.

Drug Submission Evaluation Fees	The TPP uses a component approach to determining drug submission evaluation fees (i.e., each component of the drug submission evaluation is separately costed). Therefore, the total payable is the sum of the fees for all components applicable to that particular submission. A provision is available which allows a sponsor to apply for a fee reduction based on the anticipated sales of the product in the first three years of marketing. The fee payable is limited to 10% of the aggregate anticipated sales. If actual sales after 3 years are higher than the originally predicted sales the fee owed is adjusted. A fee of $1,000 is charged to evaluate the sponsor's case.

2.3 DRUG MASTER FILE FEES

When implemented:	January 1, 1996
What a Drug Master File is:	A Drug Master File (DMF) contains proprietary information about specific components (e.g., packaging materials, colourants, flavours) used in the manufacturing processing and packaging of a drug. The TPP needs to know this information to ensure acceptability of the components. However, companies who use the components in their products do not necessarily have access to this information.
What the fee pays for:	The TPP activities related to maintaining the DMF – registration, letters of authorization.
Who must pay:	DMF owners applying for registration and/or authorizing release of information through a Letter of Access.
Payments:	Payments are made at the time of a DMF registration (original filing only), and whenever the TPP is asked to process a Letter Of Access.

2.4 DRUG EXPORT CERTIFICATE FEES

When implemented:	May 1, 1996
What a Drug Export Certificate is:	A certificate provided by the TPP to an exporter to facilitate the sale of a licensed Canadian drug in another country. The certificate is both product-specific and specific to the importing country.
What the fee pays	The TPP activities specific to the issuance of a Drug Export Certificate,

for:	in a format defined by the World Health Organization (WHO), that provides information on: • the status of a specific pharmaceutical product; and, • the Good Manufacturing Practice (GMP) status of the applicant
Who must pay:	Manufacturers/distributors applying for a Drug Export Certificate.
Payments:	Payments are due at the time of application.

2.5 DRUG ESTABLISHMENT LICENSING FEES

When implemented:	January 1, 1998
What a Drug Establishment Licence is:	A licence – required by fabricators, packagers, importers, distributors, wholesalers (Scheduled drugs only) and testers – that certifies the type of operations and products authorized to be handled by an establishment. The issuance of a licence is dependent on meeting Good Manufacturing Practice (GMP) requirements under the *Food and Drug Regulations* and, where applicable, the security requirements for narcotics and controlled substances under the *Controlled Drugs and Substances Act.*
What the fee pays for:	The TPP activities which support Drug Establishment Licensing are: • inspection/assessments conducted to ensure that drugs are fabricated, packaged, labelled, imported, distributed, wholesaled and tested in compliance with the GMP Regulations; • product analyses undertaken to assess the adequacy of an establishment's quality control department; and, • where applicable, inspections to ensure compliance with security requirements under the Regulations to the *Controlled Drugs and Substances Act.*
Who requires a Drug Establishment Licence:	The following types of establishments: • a fabricator, packager/labeller, or importer of drugs • a wholesaler of Scheduled drugs; • a drug testing laboratory, • a distributor of a drug who also holds the DIN; • a distributor of a drug listed in Schedule C, D or G to the *Food and Drugs Act* or Schedule F under the Regulations to the *Food and Drugs Act* who does not hold the DIN for the drug; and,

- a distributor of a narcotic as defined in Section 2 of the *Controlled Control Act,* who does not hold the DIN for the drug or narcotic.
- establishments who deal exclusively with natural health (e.g. herbal, vitamin, homeopathic) products are currently exempt.

Payments: Payments are for the annual period beginning January 1st.

Drug Establishment Licensing Fees: The TPP uses a component approach to determining drug establishment licensing fees. The fee is an annual charge, and is the sum of following three components, each designed to reflect the cost of the activity required.
A provision is available which allows a person to apply for a fee reduction based on historical sales data. The fee payable is limited to 1.5% of the gross revenue from the sales, testing and packaging/labeling of drugs.

3.0 THE TPP COST RECOVERY PROGRAM FOR MEDICAL DEVICES

Cost recovery for medical devices has three components The TPP has three cost recovery initiatives related to the manufacture, licensing and marketing of medical devices:

- Medical Device Licence Application Fees
- Fees for the Right to Sell a Licensed Medical Device
- Medical Device Establishment Licence Fees

3.1 MEDICAL DEVICE LICENCE APPLICATION FEES

When implemented: A licence that authorizes a manufacturer to sell a Class II, III or IV medical device in Canada.

What a Medical Device Licence is: The TPP's activities undertaken to evaluate the application by a manufacturer to sell a Class II, III or IV medical device in Canada.

What the fee pays for: Manufacturers applying for a licence to sell a Class II, III or IV medical device.

Who must pay:

Payments:

Medical Devices
License Application Fees

If the fee is less than $5,000, it is paid when the application is filed. This will generally apply to Class II and III licence applications. If the fee is greater than $5,000, then the payment schedule is as follows:

- 10% is due upon notification that the application has been screened;
- 65% is due upon notification that the application as been accepted for examination (usually concurrent with screening notification); and,
- 25% is due upon notification that the examination has been completed.

The TPP uses a component approach to determining medical devices licence application fees (i.e., each component of the medical devices licence application is separately costed). Therefore, the total fee will be determined by the number of reviews required for each component of the licence application.

A provision is available which allows a sponsor to apply for a fee reduction based on the anticipated gross revenue from sales of the medical device in Canada in the first two years of marketing. The fee payable is limited to 5% of the aggregate anticipated sales. If actual sales after the 2 years are higher than the originally predicted sales, the

fee owed is adjusted.

3.2 FEES FOR THE RIGHT TO SELL A LICENSED MEDICAL DEVICE

Will be implemented:	November 1, 1999
What the Right to Sell A Licensed Medical Device is:	A right given by the Canadian government to a manufacturer to continue to sell a licensed (Class II, III or IV) medical device in Canada.
What the fee pays for:	A portion of costs related to the TPP's medical device product post-market monitoring activities.
Who must pay:	Manufacturers who wish to market licensed Class II, III or IV medical devices in Canada.
Payments:	Payments are for the annual period beginning November 1st.
Right to Sell a Licensed Medical Device	The fee for the right to sell a licensed medical device is an annual charge, and is the sum of the fees for all class II, III or IV medical device. A provision is available which allows a manufacturer to apply for a fee reduction. The fee payable is limited to 1.5% of the annual gross revenue from sales in Canada in the previous fiscal year from all manufacturer's licensed medical devices.

3.3 MEDICAL DEVICE ESTABLISHMENT LICENCE FEES

Will be implemented:	January 1, 2000
What a Medical Device Establishment Licence is:	A licence that authorizes companies to import or distribute all Classes of medical devices. This licence is also required for manufacturers of Class I medical devices who do not sell through a licensed Canadian importer or distributor.
What the fee pays for:	The costs related to the TPP's medical device establishment post-market monitoring activities.

Who must pay:	Importers/distributors of Classes I, II, III and IV medical devices and manufacturers of Class I devices who do not sell through a licensed Canadian importer or distributor. Fees apply equally to foreign and domestic establishments.
Payments:	Payments are for the annual period beginning January 1st. A reinstatement fee is charged as required.

FEES

The following tables are presented as a guide. For definitive wording, see the applicable fee regulations. All fees are in Canadian dollars.

"Authority to Sell Drugs" Fees (See Section 2.1)

Drug Type	Fee
Drugs listed in Schedule F to the *Food and Drug Regulations*, Schedule G or D to the *Food and Drugs Act* or the Schedule to the *Controlled Drugs and Substance Act.*	$1000
Drugs that are labelled as being for use as a disinfectant of medical devices or drugs not covered by other categories	$500
Homeopathic drugs, drugs labelled for veterinary use, or disinfectants, other than those covered by the item above	$250
Any product with annual sales < $20,000	$50

Drug Submission Evaluation Fees (See Section 2.2)

	Submission Component	Submission Type	Fee
1.	Preclinical and clinical data to support a single route of administration, dosage form and condition of use	NDS	$117,000
2.	Clinical data without preclinical data, or clinical data with supplementary or confirmatory preclinical data, to support a single or additional route of administration, dosage form or condition of use	NDS, SNDS, DIN	$52,900
3.	Comparative (bioavailability, pharmacodynamic or clinical) data to support a single or additional route of administration or dosage form	all types	$17,200
4.	Comparative (bioavailability, pharmacodynamic or clinical) data required to support each additional strength	NDS, SNDS, ANDS, S/ANDS	$2,700
5.	Information and material to support (a) the removal of a drug from Schedule F to the Food and Drug Regulations, and (b) a new condition of use	SNDS	$52, 900
6.	Information and material to support the removal of a drug from Schedule F to the *Food and Drug Regulations* (same condition of use)	SNDS, ANDS	$17,200
7.	Published clinical references or other published data	all types	$2,200
8.	Chemistry and Manufacturing data for the medicinal ingredient of a drug (substance)	NAS, SNDS, ANDS, S/ANDS	$11,500
9.	Chemistry and manufacturing data to support a single dosage form (drug product)	NAS, SNDS, ANDS, S/ANDS	$15,300
10.	Chemistry and Manufacturing data	DIN&GP	$1, 500
11.	Published references to support a traditional herbal medicine	DIN	$720
12.	Information to support an application for a DIN or GP number	DIN&GP	$720
13.	Information establishing that a drug meets the requirements of a class monograph	DIN&GP	$310
14.	Administrative changes	all types	$250

Drug Master Files Fees (See Section 2.3)

Reason for Fee	Fee
To register a new DMF	$350
To process a Letter of Access	$50

Drug Export Certificate Fees (See Section 2.4)

Per certificate: $100 + appropriate tax (according to province)		
Province	**Tax**	**Total**
Quebec	7% GST + 7.5% PST	$115
New Brunswick, Nova Scotia and Newfoundland	15% HST	$115
Other Provinces	7% GST	$107

GMP Inspection Component

The fee regulations include four fee schedules in addition to specific fees for wholesalers, type (a) distributors and testers.

A. Fabrication Fees (EL Fee Regulations- section 4 and Schedule 1)

Item	Description	Fee ($CDN)
1.	Basic Fee	$6,000
2.	Each Additional Category	$1,500
3.	Dosage form classes (a) 2 classes	$3,000
	(b) 3 classes	$6,000
	(c) 4 classes	$7,500
	(d) 5 classes	$9,000
	(e) 6 classes	$10,500
	(f) each additional class	$600
4.	Sterile dosage forms	$3,000

B. Packaging/Labelling Fees (EL Fee Regulations- section 5 and Schedule 2)

Item	Description	Fee ($CDN)
1.	Basic Fee	$4,000
2.	Each Additional Category	$1,000
3.	Dosage form classes (a) 2 classes	$2,000
	(b) 3 classes or more	$3,000

C. Importation/Distribution (C01A.003(b)) (EL Fee Regulations- section 6, 7 and Schedule 3)

Item	Description	Fee ($CDN)
1.	Basic Fee	$2,500
2.	Each Additional Category	$625
3.	Dosage form classes	
	(a) 2 classes	$1,250
	(b) 3 classes	$2,500
4.	Each Fabricator	$600
5.	Each additional dosage form class for each fabricator	$300

Item 4 and 5 fees apply to importers and are based on the cost to the Programme of the activity required to establish the acceptability of foreign sites. Fees for assessment of foreign inspection reports will be $600 for each foreign fabrication site and an additional $300 for each additional dosage form class at that foreign site. Should the licensee choose to have a TPP inspector conduct a foreign assessment, the fee is not specified in the Establishment Licensing Fees Regulations, but is captured under separate contract authority. Where a favourable TPP inspection has been done, the $600 and $300 fee do not apply.

D. Distribution (C.01A.003(a)) and
Wholesaling (EL Fee Regulations- section 9) $1,500

E. Testing (EL Fee Regulations- section 10) $1,000

Drug Analysis Component

Item	Description	Fee ($CDN)
1.	Vaccines	$10,000
2.	Schedule D Drugs which are not vaccines or whole blood and its components	$4,000
3.	Drugs for Human Use listed in Schedule F to the Food and Drug Regulations or controlled drugs or narcotics	$3,000

4.	Drugs with DINs or GPS (not included in any other item)	$1,500
5.	Drugs for veterinary use	$250

Controlled Substances Component

The maximum fee for a Dealers licence for controlled drugs or narcotics or both is $1750. The definition of site applies to this security inspection component of the fee in the same way that the GMP inspection component of the fee is site specific.

Medical Device Licence Application Fees (Section 3.1)

Component of the application	Device Class	Fee ($)
Examination of a medical device licence application and/or reinstatement for a medical device for which the licence has been suspended by Health Canada or cancelled by the manufacturer.	II	$200
Description of the medical device and the materials used in its manufacture and packaging.	III, IV	$140
Risk assessment and risk reduction measures in respect of the medical device	IV	$1,000
Specifications of the materials used in the manufacture and packaging of the medical device	IV	$680
Manufacturing process of the medical device	IV	$1,360
In the case of an *in vitro* diagnostic device:		
(*a*) pre-clinical studies	IV	$2,090
(*b*) clinical studies	IV	$3,880
In the case of a medical device other than an *in vitro* diagnostic device:		
(*a*) pre-clinical studies	IV	$3,270
(*b*) clinical studies	IV	$4,400
Process validation studies	IV	$850

Component of the application	Device Class	Fee ($)
Software validation studies	IV	$2,020
A copy of the medical device label	III, IV	$170
In the case of a medical device, other than an *in vitro* diagnostic device, manufactured from or incorporating animal or human tissue or their derivatives, objective evidence of the biological safety of the medical device	IV	$2,620
Summary and conclusions of safety and effectiveness studies	III	$1,470
In the case of a near patient *in vitro* diagnostic device, *(a)* detailed information on investigational testing	IV	$2,410
(b) summary information on investigational testing	III	$440

Fees for the Right to Sell a Licensed Medical Device (Section 3.2)

Annual gross revenue from the sale of the medical device	Fee payable for the right to sell a medical device
$20,000 or more	$100.00
Less than $20,000	$50.00

Fees for a Medical Device Establishment Licence (Section 3.3)

Reason for Fee	Fee
Issuance of initial licence	No charge in 1999
Annual renewal of licences	$2,120
Reinstatement of a revoked or suspended licence	$2,120